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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,018	01/09/2004	Bianca A. Thomae	07039-440001	8952

26191 7590 03/12/2007  
FISH & RICHARDSON P.C.  
PO BOX 1022  
MINNEAPOLIS, MN 55440-1022

EXAMINER
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GEBREYESUS, KAGNEW H

ART UNIT	PAPER NUMBER
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1656

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/12/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/755,018

Applicant(s)

THOMAE ET AL.

Examiner

Kagnew H. Gebreyesus

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-15,17-33 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) 3-7,9,10,13-15 and 17-33 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11 and 12 is/are allowed.
- 6) ☒ Claim(s) 1 and 38-41 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's response on December 28, 2006 to the Office Action dated September 28, 2006 is acknowledged. Applicants have amended claims 1, 3-10, 38. Claims 3-7, 9 and 10, 13-15, 17-33 remain withdrawn as being part of non-elected subject matter. Claims 1, 8, 38-41 are present for examination. A search is extended to the species comprising positions 1303 and 1509 recited in claim 1(d) and in Claim 5.

#### ***Claim Objections***

Claims 1, 8, 38-41 are objected to for containing non-elected subject matter. Appropriate correction is required.

#### ***Withdrawn - Claim Rejections - 35 USC § 102***

Claims 1, 8 and 38 were rejected under 35 U.S.C. 102(e) as being anticipated by Fodor et al. (US PG-PUBS 2001/0053519). This rejection is hereby withdrawn following applicant's amendment to the claims. Claim 5 also

#### ***Maintained - Claim Rejections - 35 USC § 102***

Claims 1, 38-41 were rejected under 35 U.S.C. 102(e) as being anticipated by Comings et al (US 6,660,476 B2).

Applicants argue:

"...The present claims recite that the isolated nucleic acid molecule consists essentially of a nucleic acid sequence that is at least fifteen contiguous nucleotides of SEQ ID NO: 6 or SEQ ID NO: 1. As noted in the Preliminary Amendment filed on July 13, 2006, nucleic acid molecules "consisting essentially of" the recited sequences have the basic and novel characteristic that they are able to distinguish, based upon hybridization, a nucleic acid having a PNMT sequence that contains a variant from a nucleic acid having a sequence that does not contain the variant PNMT sequence. The sequence set forth in the Comings et al. patent that contains positions 1303 and 1509 of instant SEQ ID

NO:1 is 4174 nucleotides in length. The sequence of Comings et al. would not distinguish, based upon hybridization, a nucleic acid having a PNMT sequence that contains a variant from a nucleic acid having a sequence that does not contain the variant PNMT sequence. Thus, this sequence does not consist essentially of a nucleic acid sequence that is at least fifteen contiguous nucleotides of SEQ ID NO: 1..."

Coming et al's teaching is drawn to use of two single nucleotide polymorphisms identified at positions -G182A and -G387A. These positions correspond to positions 1301 and 1509 of SEQ ID NO: 1 in the instant Application. Claims 1-6 in Coming et al teaches a method of determining risk in an individual for a neuropsychiatric disorder which comprises determining the genotype of an individual by analyzing polymorphisms at nucleotide positions -387 and -182 of the PNMT gene and correlating the genotype with a predetermined risk for said disorder. Coming et al disclose various means of detecting polymorphism in the PNMT gene. As previously explained, page 8 line 42-52 of Coming et al discloses use of allele specific oligonucleotide probes of about 30 nucleotides derived from PNMT. Furthermore Coming et al teach hybridization of allele-specific probes with amplified PNMT sequences. These allele specific probes are to be used for the detection of variants of PNMT using hybridization methods.

Furthermore in Example 1, page 28, 18 mer oligonucleotide primers were used to amplify a 101 base pair region comprising position -G182A and an 86 base pair region comprising position G387A.

The specific mutations comprising position -G182A and position -G387A correspond to positions 1301 and 1509 in SEQ ID NO: 1. These sequences are within the limitation of at least 15 base pairs as defined in Applicants specification on page 8, line 23-26. The recitation "consisting essentially of" is an open language, thus this term

Art Unit: 1656

is understood as "comprising" without a definition in the specification. Claims 1, 38-41 comprise isolated nucleic acid molecules of at least 15 nucleotides wherein said nucleic acid comprises position 1301 or 1509 (comprising positions -G182A and -G387A of Comings et al.).

Thus Applicant's argument that the sequence of Comings et al. would not distinguish, based upon hybridization, a nucleic acid having a PNMT sequence that contains a variant from a nucleic acid having a sequence that does not contain the variant PNMT sequence, is not found persuasive. For this reason the rejection of claims 1, 38-41 under 35 U.S.C. 102(e) is maintained.

***Withdrawn - Claim Rejections - 35 USC § 102***

Claim 1 was rejected under 35 U.S.C. 102(b) as being anticipated by a polynucleotide sequence submitted GenBank with the accession No. AC079199.9 submitted (23-AUG-2000). This rejection is hereby withdrawn following applicant's argument.

***Withdrawn - Claim Rejections - 35 USC § 102***

Claim 1 was rejected under 35 U.S.C. 102(b) as being anticipated by Chin et al. (On the Preparation and Utilization of Isolated and Purified Oligonucleotides March 9, 2002). Applicant's argument has been considered carefully. Previous claim 1 was rejected because it recited a structure of a polynucleotide without description of any function. As broadly interpreted this claim also encompasses a 10-mer-oligonucleotide sequence (-5' CCAGTGTGTC 3') as disclosed by Chin et al. However Applicants have amended

claim 1 by reciting "at least 15 nucleotides". Therefore this rejection is hereby withdrawn.

Claims 11 and 12 are allowable.

This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply,

Art Unit: 1656

or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagne H. Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5:30pm.

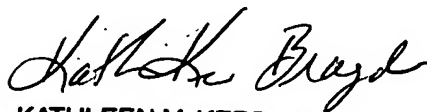
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Examiner: Kagne Gebreyesus PhD.

Feb. 26, 2007

KHG

  
KATHLEEN M. KERR, PH.D.  
SUPERVISORY PATENT EXAMINER